DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

'99 MAY -7 P3:42

Re: Monostrut™ Cardiac Valve Prosthesis
Docket No.: 98E-0779

MAY - 5 1999

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,343,049, filed by Alliance Medical Products Limited, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Monostrut™ Cardiac Valve Prosthesis, the medical device claimed by the patent.

The total length of the regulatory review period for Monostrut™ Cardiac Valve Prosthesis is 5,620 days. Of this time, 1,729 days occurred during the testing phase and 3,891 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: May 14, 1982.

   FDA has verified the applicant's claim that the date the Investigational Device Exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on May 14, 1982.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: February 5, 1987.

   The applicant claims May 8, 1986, as the date the Premarket Approval Application (PMA) Monostrut™ Cardiac Valve Prosthesis] (PMA P970002) was initially submitted. However, FDA records indicate that PMA P970002 was submitted on February 5, 1987

3. The date the application was approved: September 30, 1997.

   FDA has verified the applicant's claim that PMA P970002 was approved on September 30, 1997.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Gordon H. Olson
Sixteenth Floor
620 Newport Center Drive
Newport Beach, CA 92660

DATE: MAY - 5 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for Monostrut™ Cardiac Valve Prosthesis
Docket No. 98E-0779, FRDTS# OC99127

Attached is a FR Notice for the medical device, Monostrut™ Cardiac Valve Prosthesis. This document has been internally reviewed and cleared by OHA.

Please note that Monostrut™ Cardiac Valve Prosthesis is a trademark. Therefore, the superscript "TM" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.

«FR_Track_No»

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

7331 '99 MAY -7 P3:42

Memorandum

Date: MAY - 5 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for **Monostrut™ Cardiac Valve Prosthesis**

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned medical device under the Docket Number **98E-0779** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,343,049**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

98E-0779